DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 21,2015

Alliance Global Technology Co., Ltd.
Yayuan Chang
2F., No.92, Luke 5th Rd., Luzhu Dist.,
Kaohsiung City 82151, Taiwan

Re: K142557
Trade/Device Name: Anker Dental Implant System - SB-III, ST and AT Series
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: August 21, 2015
Received: August 25, 2015

Dear Yayuan Chang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner DDS, MA

Erin Keith
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K142557

Device Name: Anker Dental Implant System – SB-III, ST and AT series

Indications for Use:

Anker Dental Implant System is intended to be surgically placed in the alveolar bone of upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function.

Anker Dental Implant System is intended for delayed loading. No matter placing implants in anterior or posterior region, we recommend choosing the diameter of implants as large as possible. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants through the corresponding components (abutments).

Specific indications for small diameter (ϕ 3.3mm) and short (length < 7mm) dental implants:
Because of their reduced mechanical stability, small diameter and short implants are only used in cases with a low mechanical load. We recommend only used in the mandibular anterior region and maxillary lateral incisor.

Prescription Use __X__ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) SUMMARY K142557

Anker Dental Implant System – SB-III, ST and AT series

1. **Company Name**: Alliance Global Technology Co., Ltd.
   2F., No.92, Luke 5th Rd., Luzhu Dist., Kaohsiung City 821, Taiwan (R.O.C.)
   Telephone: +886-7-695-6688
   Fax: +886-7-695-5329
2. **Contact Person**: Ms. Yayuan Chang
   E-mail: ketty@anchorfast.com.tw

3. **Date prepared**: Sep. 5th, 2014

4. **Trade Name**: Anker Dental Implant System – SB-III, ST and AT series
   Common Name: Dental Implant
   Classification Name: Root-form endosseous dental implant

5. **Device Classification**: Class II

6. **Regulation Number**: 21 CFR 872.3640
   Panel: Dental
   Product Code: DZE

7. **Predicate Devices:**

K131165	Anker Dental Implant System (Primary Predicate for proposed fixtures SB-III, ST, and proposed abutments SB-III)
K123784	Straumann Dental Implant System SLA & SLActive & Roxolid Product Families (Reference Predicate for proposed fixture AT, ST)
K130808	Straumann healing abutments, healing caps, closure screws (Reference Predicate for proposed abutments of ST and AT)
K120822	Straumann CARES Variobase Abutments (Reference Predicate for proposed abutments of ST and AT)
K121585	Osstem TS Implant System (Reference Predicate for proposed abutment SB-III)
K052957	Dentium Implantium Prosthetics (Reference Predicate for proposed abutment SB-III)

8. Device Description:

Anker Dental Implant System is an integrated system which includes Bone Level (SB-III series) and Tissue Level (ST and AT series) dental implants.

Anker Dental Implant System SB-III series consists of fixture, abutments (healing abutment, fixed abutment, dual abutment, angle abutment, o-ring abutment,

temporary abutment, convertible abutment, convertible protect cap, convertible combination cylinder, convertible angled cylinder, convertible temporary cylinder, angled screw abutment, temporary cylinder) and cover screw.

Anker Dental Implant System ST and AT series consist of fixture, abutments (healing cap, solid abutment, cementable abutment, angled abutment, temporary restoration screw, screw retained abutment, locator abutment) and closure screw.

Fixtures are made of pure titanium (grade IV) and there surface was treated by SLA (Sand-blasted, Large grit, Acid-etched) process. Diameters of fixtures are including 3.3 to 5.0 mm and lengthes are including 7.0 to 15.0 mm. Cover screw, closure screw and most abutments are made of titanium alloy. Temporary abutment and convertible temporary cylinder (SB-III series) are made of SUS316L stainless steel instead of titanium alloy. All products are sterilized as finished products.

Fixture of Anker Dental Implant System SB-III series is substantially equivalent in design, function and intended use to the Anker Dental Implant System (K131165). Fixture of AT series is substantially equivalent in design, function and intended use to the Straumann Dental Implant System (K123784). And fixture of ST series is substantially equivalent in design, function and intended use to the Anker Dental Implant System (K131165) and Straumann Dental Implant System (K123784).

Abutment of Anker Dental Implant System SB-III series is substantially equivalent in design, function and intended use to the Anker Dental Implant System (K131165), TS Implant System (K121585) of Osstem Implant Co., Ltd. and Implantium Prosthetics (K052957) of Dentium Co., Ltd. Abutment of ST and AT series are substantially equivalent in design, function and intended use to the Straumann healing abutments, healing caps, closure screws (K130808) and Straumann CARES Variobase Abutments (K120822).

9. Indications for Use:

Anker Dental Implant System is intended to be surgically placed in the alveolar bone of upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function.

Anker Dental Implant System is intended for delayed loading. No matter placing implants in anterior or posterior region, we recommend choosing the diameter of implants as large as possible. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants through the corresponding components (abutments).

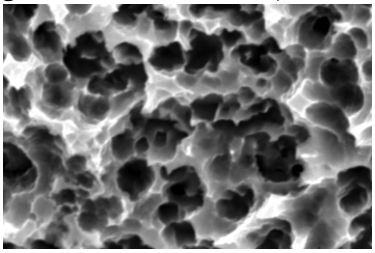
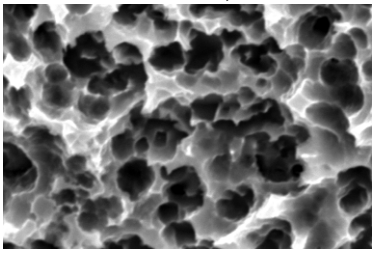
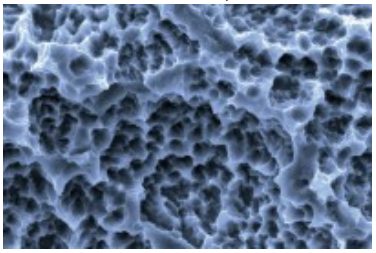
Specific indications for small diameter (∅3.3mm) and short (length < 7mm) dental implants:

Because of their reduced mechanical stability, small diameter and short implants are only used in cases with a low mechanical load. We recommend only used in the mandibular anterior region and maxillary lateral incisor.

10. Substantial Equivalence:

The following tables list the proposed devices Anker Dental Implant System – SB-III, ST and AT series and the respective predicate which Anker is claiming substantial equivalence to.

	Item	Anker Dental Implant System SB-III, ST and AT series	Anker Dental Implant System	Straumann Dental Implant System SLA , SLActive and Roxolid Product Families
1	**510K No.**	-------	K131165	K123784
2	**Design**	**SB-III**  **ST**  **AT-I**  **AT-II**  **AT-III** 		
3	**Intended Use**	Anker Dental Implant System is intended to be surgically placed in the alveolar bone of upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function. Anker Dental Implant System is intended for delayed loading. No matter placing implants in anterior or posterior region, we recommend choosing the diameter of implants as large as possible. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants through the corresponding components (abutments). Specific indications for small diameter (∅3.3mm) and short (length < 7mm) dental implants:	Anker Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function.	Straumann® Dental implants are indicated for oral endosteal implantation in the upper and lower jaw arches for the functional and aesthetic oral rehabilitation of edentulous and partially dentate patients. Straumann® Dental implants are also indicated for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants

		Because of their reduced mechanical stability, small diameter and short implants are only used in cases with a low mechanical load. We recommend only used in the mandibular anterior region and maxillary lateral incisor.		through the corresponding components (abutments). In cases of fully edentulous patients, 4 or more implants must be used in immediately loaded cases.
4	**Material**	Titanium	Titanium	Titanium
5	**Body Diameter**	**SB-III and ST series:** 3.5mm, 4.0mm, 4.5mm, 5.0mm **AT series:** 3.3mm, 4.1mm, 4.8mm	3.4mm, 3.5mm, 3.8mm, 4.0mm, 4.3mm, 4.5mm, 4.8mm, 5.0mm	3.3mm, 4.1mm, 4.8mm
6	**Length**	**SB-III and ST series:** 7mm, 8.5mm, 10mm, 11.5mm, 13mm, 15mm **AT series:** 8mm, 9mm, 10mm, 11mm, 12mm, 13mm, 14mm, 15mm	7mm, 8mm, 8.5mm, 10mm, 11.5mm, 12mm, 13mm, 14mm, 15mm	6mm, 8mm, 10mm, 12mm, 14mm, 16mm
7	**Design of fixture body**	**SB-III and ST series:** tapered design. **AT series:** Straight design.	Tapered design	Straight design
8	**Platform Switching**	**SB-III series:** YES **ST & AT series:** NO	YES	NO
9	**Internal connection**	**SB-III series:** Internal hex connection and 11°morse taper structure. **ST & AT series:** Internal octa connection and 8°morse taper structure.	Internal hex connection and 11°morse taper structure.	Internal octa connection and 8°morse taper structure.
10	**Thread design**	**SB-III and ST series:** combined with micro thread (0.45mm pitch distance, fourfold thread) and macro thread (0.9mm pitch distance, double thread) structure. **AT series:** same pitch distance on whole fixture body.	Combined with micro thread (0.45mm pitch distance, fourfold thread) and macro thread (0.9mm pitch distance, double thread) structure.	Same pitch distance on whole fixture body.
11	**Apex design**	**SB-III and ST series:** three blade self tapping design and blunt end structure. **AT series:** no blade design and round end structure.	Three blade self tapping design and blunt end structure.	No blade design and round end structure.
12	**Surface Treatment**	S.L.A. (Sand-blasted, Large grit, Acid-etched surface) 	S.L.A. (Sand-blasted, Large grit, Acid-etched surface) 	S.L.A. (Sand-blasted, Large grit, Acid-etched surface) / SLActive 

13	**Sterilization**	γ-ray (Radiation)	γ-ray (Radiation)	γ-ray (Radiation)
14	**Material of Abutments**	Titanium alloy and stainless steel	Titanium alloy and stainless steel	Titanium and titanium alloy

When compared to the predicate devices, Anker Dental Implant System (K131165) and Straumann Dental Implant System (K123784), Anker Dental Implant System SB-III, ST and AT series are equivalent in surface treatment, intended use, method of operation, material and design.

11. Non-clinical Testing:

Overview all non-clinical testing:

Testing Item	**Reference**
Compressive forces and fatigue tests	ISO14801
Compatibility test of dental implant/abutment interface	N/A
Corrosion test	ASTM G3-89
Residual of Acidic Substances Test	ISO10993-12
Biocompatibility test	ISO10993-3 ISO10993-5 ISO10993-6 ISO10993-10 ISO10993-11 Pharmacopeia US OECD guideline #473 OECD guideline #474
Sterilization validation of GAMMA irradiation	ISO11137-1
Shelf life Validation	ASTM F88/F88M-09 ASTM F1140-07 ASTM F1929-98 ISO11737-2

Non-clinical test was used to support the decision of substantial equivalence. Non-clinical testing consisted of performance of testing in accordance with the FDA guidance “Class II Special Controls Guidance Document Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments.” The results of the non-clinical testing demonstrate that the Anker Dental Implant System – SB-III, ST and AT series are substantially equivalent to the predicate devices.

12. Clinical Testing:

No clinical studies are submitted.

13. Conclusion:

The evaluation of the Anker Dental Implant System – SB-III, ST and AT series do not raise any additional concerns regarding substantial equivalence and Anker Dental Implant System – SB-III, ST and AT series may therefore be considered substantially equivalent to their predicate device.